No. 17-290

IN THE

Supreme Court of the United States

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

DORIS ALBRECHT, ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

SUPPLEMENTAL BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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The United States agrees that the Third Circuit's approach to drug preemption is misguided, and that this Court's immediate review is warranted due to the "importan[ce]" and "practical implications" of the legal question. U.S. Br. 23. In this sensitive area of law, the Court has granted certiorari even when the United States has recommended *against* it. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). The same result should follow *a fortiori* here, despite the dust that Respondents now attempt to kick up.

1. Respondents begin by rehashing supposed "vehicle" problems that Merck has already rebutted. Those arguments have not improved with age or repetition. They amount to nothing, which is why the United States "ignore[d]" them. Supp. Br. 2.

First, there is no reason why this Court would have to "confront" the purportedly "threshold" issue of the district court's (perfectly proper) show-cause procedure. Supp. Br. 1. The Third Circuit bypassed that issue entirely, and Respondents do not claim it poses any jurisdictional obstacle. At most, it could therefore be an issue to address on remand after this Court vacates the Court of Appeals' erroneous legal ruling on the merits. *See* Merck Reply 10.

Second, the record is hardly "under-developed." Supp. Br. 2. The trial court gave Respondents ample opportunity to develop evidence in opposition to the preemption defense (*see* Pet.App.136a), and the only "missing" evidence that Respondents identify is an unrequested deposition of a Merck employee about her notes from a single phone call with FDA. The rest of the record, however, makes clear that Respondents' claims are preempted as a matter of law, even without those notes. *See* Merck Reply 5, 11; U.S. Br. 19–22.

Third, Respondents assert that, because this case will not resolve *all* claims against Merck, it is not worth resolving *any* of them. Supp. Br. 3. This Court's decision would knock out the most important theories in these myriad cases: those alleging (either directly or derivatively) that Merck should have revised the Warnings & Precautions section of the label prior to October 2010. Just as importantly, this Court's ruling would clarify a confused area of law that governs a high volume of cases with substantial policy implications. *See* U.S. Br. 23; Merck Reply 10.

2. In addition to the re-warmed arguments from their brief in opposition, Respondents now raise two new "vehicle" problems—Merck's alleged "waiver" of arguments advanced by the United States. There was no waiver. Respondents simply mischaracterize both the United States' position and Merck's.

Respondents contend that Merck never pressed the United States' theory that *Wyeth v. Levine*, 555 U.S. 555 (2009), is "inapplicable when FDA has made a labeling decision." Supp. Br. 4. That is semantics. The United States correctly explained that *Levine* "did not resolve how to determine the meaning and effect of an actual FDA labeling-supplement decision," as no warning had been proposed in that case. U.S. Br. 17. When FDA *has* acted on a proposal, the question is "how to interpret FDA's actual labeling decision." U.S. Br. 19. If that decision reflects a science-based rejection of a warning—as here—then contrary state-law claims are preempted. U.S. Br. 19; *see also* Merck C.A. Br. 40–53. Whether FDA's *actual* decision is characterized as "clear evidence" of what FDA *would have done*, thereby satisfying *Levine*, or instead as an *exception* to *Levine*, makes no substantive difference.

Respondents also suggest that, while the United States relies heavily on FDA's Complete Response Letter to support its interpretation of FDA's actions, Merck "barely mention[ed]" that letter below. Supp. Br. 6. Not true. Merck has consistently argued that FDA's formal response reflected the agency's science-based ground for rejecting its request. *See, e.g.*, Merck C.A. Br. 49 (citing FDA's "formal response" to show what the agency "clearly understood"); Merck Reply 5–6. To be sure, Merck has also highlighted other evidence to corroborate that interpretation of FDA's letter. But the United States equally accepts that construction of the Complete Response Letter may turn on "the surrounding regulatory framework and related FDA actions." U.S. Br. 15; *see also id.* (acknowledging that "extrinsic evidence may sometimes be relevant to determine the meaning and effect of FDA's agency action"). Again, Respondents are imagining a divergence that does not exist.

3. Last, Respondents continue to insist that the Third Circuit reached the right result, because (they say) FDA rejected Merck's proposed warning based on disapproval of Merck's terminology, "not because there was insufficient evidence" that Fosamax posed the safety risk. Supp. Br. 6. That "fact," according to Respondents, precludes Merck from prevailing on its preemption defense, or at least requires that a *jury* resolve it as a question of *fact*. Supp. Br. 6–10.

That attempt to duck the question presented was unpersuasive and at odds with the record even before the United States filed its brief (Merck Reply 3–6); it is absolutely untenable in light of what FDA has now represented about its regulatory practices in general and its decisions about Fosamax in particular.

As the United States' brief explains, regulations compel FDA to cooperate with manufacturers when there is a scientific basis for a warning; the agency does not reject warnings on "editorial" grounds. U.S. Br. 5–6. To the contrary, if FDA comes to believe that new safety information justifies a label warning, the agency is "required" by statute to notify the drug manufacturer and "engage in expedited discussions to revise the labeling." U.S. Br. 22 (citing 21 U.S.C. § 355(o)(4)). Consistent with that legal background, FDA's rejection of Merck's proposed warning "was based on the agency's determination that the data was then insufficient to justify such a warning." U.S. Br. 19. There is "[n]o sound basis" to conclude that, as Respondents insist, FDA rejected the proposal "because of [Merck's] proposed text." U.S. Br. 21.*

With FDA having now cleared away any doubt regarding the regulatory scheme and its approach to proposed warnings, nothing stands in the way of resolving the question presented: When a drug manufacturer tells FDA everything it knows about a safety risk and proposes a warning, but FDA *refuses* to approve the warning, can a lay jury nonetheless hold the manufacturer liable for its failure to warn, based on the *speculation* that the agency *might* have approved some alternatively worded warning?

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* Respondents also note that an FDA rejection might not suffice to establish preemption if FDA did not have "all relevant data" or if new data "emerg[ed] after [its] decision." Supp Br. 5. True, but this case involves neither circumstance. U.S. Br. 19 n.10. Respondents never identify any missing or new data.

* * *

Lower courts and regulated parties remain confused and uncertain about the meaning and scope of this Court's decision in *Levine*. At a minimum, this case will determine the approach to preemption in the particular context of an FDA decision rejecting a proposed warning. As the United States explains, that is a significant question in its own right, *see* U.S. Br. 22, and one that arises regularly, *see, e.g.*, *Cerveny v. Aventis, Inc.*, 855 F.3d 1091 (10th Cir. 2017); *Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015).

More generally, and as the United States further reaffirms, *see* U.S. Br. 23, this case should also shed light on broader questions, such as whether *Levine* adopted a "clear and convincing" evidence standard and whether a judge or a lay jury should decide whether a plaintiff's claims are preempted. Given the importance of this area of law to public safety, the pharmaceutical industry, and FDA's mission—as now confirmed by the United States—this Court should grant review to provide the requisite guidance.

CONCLUSION

The petition should be granted.

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